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CLMPTO

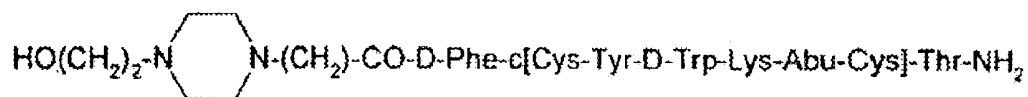
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CLAIMS 1-7 (ORIGINAL)

1. A process for making Compound (I), where Compound (I) comprises Compound (A),



(A)

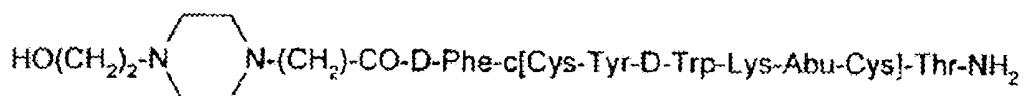
and a polymer, wherein the polymer comprises lactide units, glycolide units and tartaric acid units where the ratio in the polymer of the lactide units is from and including 71% to 73%; of the glycolide units is from and including 26% to 28%; and of the tartaric acid units is from and including 1% to 3%; and where the amino group of Compound (A) is ionically bonded to a carboxylic group of the acid units of the polymer;

said process comprising the step of reacting an aqueous solution of Compound (A) with the polymer or a salt thereof, in a mixture of acetonitrile and water wherein the weight ratio of acetonitrile to water is about 3 to 1, respectively, at a temperature of about 0°C to 5°C until the formation of Compound (I) is substantially complete.

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2. A process according to claim 1 wherein, the temperature is about 2.5°C; and said process comprises the additional step of isolating Compound (I).

3. A process for making microparticles of Compound (I), where Compound (I) comprises Compound (A),



(A)

and a polymer, wherein the polymer comprises lactide units, glycolide units and tartaric acid units where the ratio in the polymer of the lactide units is from and including 71% to 73%; of the glycolide units is from and including 26% to 28%; and of the tartaric acid units is from and including 1% to 3%; and where the amino group of Compound (A) is ionically bonded to a carboxylic group of the acid units of the polymer;

said process comprising the steps of:

nebulizing an ethyl acetate solution of Compound (I) into isopropyl alcohol to obtain a dispersion of microparticles of Compound (I),

wherein the concentration of Compound (I) in the ethyl acetate solution is about 8% to about 12% (W/W); the rate of spraying the solution of Compound (I) from the nebulizer into the isopropyl alcohol is about 4.9 ml/minute to about 5.1 ml/minute; the frequency setting of the nebulizer is such that the nebulizer does not spit the ethyl acetate solution of Compound (I); the volume of isopropyl alcohol is about 20 to 30 times volumetric excess compared to the ethyl acetate volume; and the temperature of isopropyl alcohol is about -60°C to about -78°C ;

allowing the isopropyl alcohol to warm to about 0°C to 22°C ; and isolating said microparticles from the isopropyl alcohol.

4. A process according to claim 3, wherein the rate of spraying is about 5 ml/minute and the volume of isopropyl alcohol is about 20 times volumetric excess compared to the volume of ethyl acetate.

5. A process according to claim 4, wherein the polymer comprises about 72% lactide units, about 27% glycolide units and about 1% tartaric acid units.

6. A process according to claim 5, wherein the microparticles have a mean size of about 10 microns to about 100 microns.

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7. A process according to claim 6, wherein the microparticles have a mean size of about 40 microns to about 70 microns.

CLAIMS 8-9 (CANCELED)